



**1.0 PURPOSE**

This guideline is used to facilitate the manufacturing and repacking activities in the Galenical/ Manufacturing pharmacy unit.

**2.0 TERMINOLOGY**

- DD : Dangerous Drug
- FIFO : First In First Out
- FEFO : First Expired First Out
- HA : Health Assistant
- HSAAS : Hospital Sultan Abdul Aziz Shah
- P : Pharmacist
- PA : Pharmacist Assistant

**3.1 Management of Galenical Preparation**

No.	Description	Person In Charge
1.0	<p><b>SCREEN FORMULATION REQUIRED</b></p> <ul style="list-style-type: none"> <li>i. Identify type of formulation and quantity to be prepared.</li> <li>ii. Identify based on request and usage. Enter work order after product identification.</li> </ul>	P/PA
2.0	<p><b>WORKSHEET PREPARATION</b></p> <ul style="list-style-type: none"> <li>i. Prepare a worksheet and generate labels.</li> <li>ii. Worksheet must contain: -               <ul style="list-style-type: none"> <li>• Volume manufactured</li> <li>• List of all ingredients in the formulation and weight required</li> <li>• Name of the person prepared and countercheck</li> <li>• Batch number and expiry date of the product</li> <li>• Process of preparation</li> </ul> </li> <li>iii. Label of formulation must contain: -               <ul style="list-style-type: none"> <li>• Drug name and strength</li> <li>• Batch Number and expiry date</li> <li>• Packing size</li> <li>• Preparation date</li> <li>• Storage condition</li> </ul> </li> <li>iv. Issue raw material from sub store to working station.</li> </ul>	P/PA
3.0	<p><b>COUNTERCHECK</b></p> <ul style="list-style-type: none"> <li>i. Countercheck worksheet, label and material.</li> <li>ii. Clarify any correction or modification as needed.</li> </ul>	P/PA



**GUIDELINE FOR MANUFACTURING & REPACKING**

No.	Description	Person In Charge
4.0	<p><b>PREPARATION</b></p> <p>i. Check the condition of the equipment used at the working station. All personnel must wear appropriate personal protective equipment throughout the process activity.</p> <p>ii. Prepare the product according to the method stated in worksheet.</p> <p>iii. External and internal preparation must be prepared at different area.</p> <p>iv. Only Pharmacists are authorised to prepare DD-related formulations.</p>	P/PA
5.0	<p><b>REPACKING</b></p> <p>i. Prepack bulk quantity products into desired size.</p> <p>ii. Calculate percentage of yield and record into worksheet. Ensure that the yield percentage is within range (95 -100%) to avoid discrepancy investigation.</p>	P/PA
6.0	<p><b>FINAL PRODUCT</b></p> <p>Seal and label final product accordingly and arrange according to FIFO/ FEFO basis.</p>	P/PA
7.0	<p><b>UPDATE STOCK LEVEL</b></p> <p>Update bin card (manual) inventory.</p>	P/PA

**3.2 Management of Pre-packing activities**

No.	Description	Person In Charge
1.0	<p><b>SCREEN PRE PACK PRODUCTS</b></p> <p>Identify Items and quantities to be pre-packed.</p>	PA/HA
2.0	<p><b>WORKSHEET PREPARATION</b></p> <p>i. Prepare worksheet containing:</p> <ul style="list-style-type: none"> <li>• Item and quantity to be pre-packed</li> <li>• Batch number</li> <li>• Packing size</li> <li>• Pre-pack quantity</li> </ul> <p>ii. Prepare a label based on a worksheet.</p> <p>iii. Label shall consist of:</p> <ul style="list-style-type: none"> <li>• Name and strength of the drug</li> <li>• Packing size</li> <li>• Batch number</li> <li>• Expiry date</li> <li>• Pre-pack date</li> <li>• Manufacturer name</li> <li>• “Controlled Medicine” and “Keep away from children”</li> </ul>	PA/HA



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**GUIDELINE FOR MANUFACTURING & REPACKING**

No.	Description	Person In Charge
3.0	<b>PREPACKING</b> i. Quantity and packing size of pre-pack should be match with the worksheet. ii. Only one batch shall be packed at one time. Different batch shall not be pre-packed together.	PA/HA
4.0	<b>COUNTERCHECK</b> i. Pre-packed medicine shall be check and verified by another pharmacy staff prior to storage. ii. Percentage of yield is calculated and recorded. If any discrepancy should be investigated.	PA/HA
5.0	<b>STORAGE</b> i. Store the pre-packed medicine according to specifications of manufacturer. ii. Update and document pre-packed stock inventory.	PA/HA